510(k) Summary

ArthroCare® Corporation

SmartStitch® M-Connector Ultra System

JUL 12 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Cheryl Frederick Director, Regulatory Affairs
Date Prepared:	April 27, 2012

Device System Names/Components

Proprietary:	SmartStitch M-Connector Ultra	
	Common:	Arthroscopic Instrument
	Classification:	Class I
	Product Code:	NBH
	CFR Section:	21 CFR 888.1100
Proprietary:	SmartStitch Handle	
	Common:	Arthroscopic Instrument
	Classification:	Class I
	Product Code:	NBH
	CFR Section:	21 CFR 888.1100
Proprietary:	Suture Cartridge containing MagnumWire® Suture	
	Common:	Suture, Nonabsorbable, Synthetic, Polyethylene
	Classification:	Class II
	Product Code:	GAT
	CFR Section:	21 CFR 878.5000

Predicate Device

The SmartStitch M-Connector Ultra System is substantially equivalent to the ArthroCare M-Connector System cleared under K023843 (February 14, 2003) and K033317 (December 30, 2003), to the ArthroCare PerfectPasser® Connector System cleared under K062244 (October 2, 2006).

Description

The SmartStitch M-Connector Ultra System is an orthopedic/arthroscopic instrument for mechanically delivering sutures through soft tissue based on the basic design concepts of handheld, manual suture passers.

The handle is provided non-sterile. The connector and suture cartridge are sterilized by ethylene oxide. The finished products are packaged in a Tyvek® pouch inserted into a chipboard carton. Testing was performed to demonstrate the proposed device is substantially equivalent to the predicate devices.

Intended Use/Indications For Use
The SmartStitch M-Connector Ultra System is indicated for use in the placement of suture(s) through soft tissue in arthroscopic and limited access procedures.

Non-Clinical Data
Bench testing was performed on both the proposed and predicate devices. The test results demonstrate that the SmartStitch M-Connector Ultra System meets all design, performance, and safety specifications. Based on the test results, the proposed device is substantially equivalent to the predicate devices.

Clinical Data
No clinical or animal data are included in this submission.

Summary
All testing demonstrates that the SmartStitch M-Connector Ultra System performs as intended and has acceptable mechanical properties when used in accordance with its labeling.
As the SmartStitch M-Connector Ultra System's intended use and technological characteristics are comparable to the predicate devices, we believe that the device is substantially equivalent to the ArthroCare SmartStitch M-Connector System and ArthroCare SmartStitch PerfectPasser System. The minor differences between the subject and predicate devices do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthocare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive, Building One
Austin, Texas 78735

JUL 12 2012

Re: K121306
Trade/Device Name: SmartStitch® M-Connector Ultra System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, NBH
Dated: June 25, 2012
Received: June 26, 2012

Dear Ms. Frederick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Alberto Gutierrez

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121306

Device Name: SmartStitch® M-Connector Ultra System

Indications for Use:
The SmartStitch® M-Connector Ultra System is indicated for use in the placement of suture(s) through soft tissue in arthroscopic and limited access procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121306